4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0766]

Hospira, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 21 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040140	Diphenhydramine Hydrochloride (HCl) Injection, 50 milligrams (mg)/milliliters (mL)	Hospira, Inc., 275 North Field Dr., Building H1-3S, Lake Forest, IL 60045
ANDA 040578	Benzphetamine HCl Tablets, 50 mg	ScinoPharm Taiwan, Ltd., 909 N. Ford Ave., Fullerton, CA 92832

ANDA 065267	Cefprozil Tablets, 250 mg, and 500 mg	Bionpharma Inc., 600 Alexander Rd., Suite 2-4B, Princeton, NJ 08540
ANDA 065284	Cefprozil Oral Suspension, 125 mg/5 mL and 250 mg/5 mL	Do.
ANDA 065301	Cefadroxil Tablets, Equivalent to (EQ) 1 gram (g) base	Do.
ANDA 065307	Cefadroxil Oral Suspension, EQ 250 mg base/5 mL and EQ 500 mg base/5 mL	Do.
ANDA 065309	Cefadroxil Capsules, EQ 500 mg base	Do.
ANDA 065326	Cephalexin Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
ANDA 076720	Morphine Sulfate Extended Release Tablets, 30 mg, and 60 mg	Nesher Pharmaceuticals (USA) LLC., 13910 Saint Charles Rock Rd., Bridgeton, MO 63044
ANDA 076733	Morphine Sulfate Extended Release Tablets, 15 mg	Do.
ANDA 077855	Morphine Sulfate Extended Release Tablets, 100 mg and 200 mg	Do.
ANDA 080225	Potassium Chloride Injection, 2 milliequivalent (mEq)/mL and 3 mEq/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 202393	Diclofenac Sodium Topical Solution, 1.5%	TWi Pharmaceuticals, Inc., 536 Vanguard Way, Brea, CA 92821
ANDA 203581	Glyburide Tablets, 1.25 mg, 2.5 mg, and 5 mg	Sunny Pharmtech Inc., 175 SW 166th Ave., Pembroke Pines, FL 33027
ANDA 204137	Omeprazole and Sodium Bicarbonate Capsules, 20 mg; 1.1 g	Unicorn Pharmaceuticals, 5 Links Circle, Durham, NC 27707
ANDA 206588	Dextroamphetamine Sulfate Tablets, 5 mg, and 10 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 208263	Doxycycline Hyclate Capsules, EQ 50 mg base and EQ 100 mg base	Do.
ANDA 209111	Dextroamphetamine Sulfate Extended Release Capsules, 5 mg, 10 mg, and 15 mg	Do.
ANDA 210079	Oxycodone and Acetaminophen Tablets, 325 mg; 2.5 mg, 325 mg; 5 mg, 325 mg; 7.5 mg, 325 mg; 10 mg	Do.
ANDA 210080	Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and	Do.

	Amphetamine Sulfate Extended Release Capsules, 1.25 mg; 1.25 mg; 1.25 mg; 1.25 mg, 2.5 mg; 2.5 mg; 2.5 mg; 2.5 mg, 3.75 mg; 3.75 mg; 3.75 mg; 3.75 mg, 5 mg; 5 mg; 5 mg; 5 mg, 6.25 mg; 6.25 mg; 6.25 mg; 6.25 mg, 7.5 mg; 7.5 mg; 7.5 mg; 7.5 mg.	
ANDA 211543	Butalbital, Acetaminophen, and Caffeine Tablets, 325 mg; 50 mg; 40 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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